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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte THOMAS A. AFZAL

Appeal 2015-002598
Application 12/060,191
Technology Center 3700

Before: JOHN C. KERINS, WILLIAM A. CAPP, and
ARTHUR M. PESLAK, *Administrative Patent Judges*.

CAPP, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant seeks our review under 35 U.S.C. § 134 of the final rejection of claims 1–6 and 8–28. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

THE INVENTION

Appellant's invention is a prosthetic intervertebral disc. Spec. ¶¶ 2–3.

Claim 1, reproduced below, is illustrative of the subject matter on appeal.

1. A prosthetic intervertebral disc for inserting in an intervertebral space between two adjacent vertebrae in a spine, comprising:

a.) a first end plate;

b.) a second end plate;

c.) at least one core member comprising a fillable noncompliant balloon having a first unfilled configuration and a second filled configuration, positioned between said first and second end plates; and

d.) at least one fiber extending between and engaged with said first and second end plates; and

wherein said end plates and said core member are held together by said at least one fiber and wherein the disc is configured to be insertable into the intervertebral space when the fillable noncompliant balloon is in the unfilled configuration and wherein the fillable noncompliant balloon is configured to be filled to the filled configuration after being inserted in the intervertebral space.

THE REJECTIONS

The Examiner relies upon the following as evidence in support of the rejections:

Stubstad	US 3,867,728	Feb. 25, 1975
Trieu	US 2004/0133280 A1	July 8, 2004
Kim '364	US 2005/0027364 A1	Feb. 3, 2005
Bao	US 2005/0033437 A1	Feb. 10, 2005
Kim '500	US 2005/0228500 A1	Oct. 13, 2005

The following rejections are before us for review:

1. Claims 1–6 and 17–19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bao and Stubstad.

2. Claims 8 and 20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bao, Stubstad, and Trieu.

3. Claims 9, 13, 21, and 25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bao, Stubstad, and Kim '364.

4. Claims 10–12, 14–16, 22–24, and 26–28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bao, Stubstad, Kim '364, and Kim '500.

OPINION

Obviousness of Claims 1–6 and 17–19 as unpatentable over Bao and Stubstad

Claim 1

The Examiner finds, among other things, that Bao discloses a prosthetic intervertebral disc. Final Action 2 (citing Bao, Fig. 34 element 10). The Examiner finds that Bao's "disc" is configured to be insertable into an intervertebral space as claimed. *Id.* (citing Bao ¶¶ 92–95). The Examiner relies on Stubstad as teaching the use of fibers that extend between and engage the end plates of a prosthetic disc. *Id.* at 3. The Examiner concludes that it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a fiber, as taught by Stubstad, to connect the pieces of Bao's prosthetic disc. *Id.* According to the Examiner, a person of ordinary skill in the art would have done this to connect the end plates and core member together. *Id.*

Appellant traverses the rejection by arguing, among other things, that Bao does not disclose a disc replacement and, instead, discloses a replacement for the nucleus of a disc. Appeal Br. 13. Appellant emphasizes

that Bao leaves the annulus naturally surrounding the disc nucleus substantially in place. *Id.*

The Examiner, in the Answer, does not respond to Appellant's position regarding Bao being directed to nucleus replacement instead of an intervertebral disc prosthesis. Ans. 2–4.

Bao is directed to a device for replacing a damaged nucleus of a disc. Bao, Abstract. Bao differentiates between devices that constitute a “total disc prosthesis,” where the entire spinal disc is replaced after radical discectomy, and a “disc nucleus prosthesis,” that is used to replace only the nucleus of a spinal disc after a nucleotomy while retaining the annulus of the disc. *Id.* ¶ 9–10. Bao's device is sized to fit within the annulus and is used in surgical procedures commensurate with such size. *Id.* ¶¶ 81, 82. The periphery of Bao's shells 12, 14 contacts and places in tension the inner surface of the annulus. *Id.* ¶ 76. Such tension is reported as improving the stability of the intervertebral joint.

[T]he shells 12, 14 of the implant 10 do not necessarily replicate the shape of the natural nucleus so that the periphery 26 of the implant 10 may abut and stretch portions of the annulus, thereby providing tension to those portions of the annulus. It has been found that tension on the annulus alleviates pain and improves stability of the intervertebral joint.

Id. ¶ 84.

In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art. *In re Piasecki*, 745 F.2d 1468, 1471–72 (Fed. Cir. 1984). The patent applicant may then attack the Examiner's prima facie determination as improperly made out, or the applicant may present objective evidence tending to support a conclusion of nonobviousness. *In re*

Fritch, 972 F.2d 1260, 1265 (Fed. Cir. 1992). However, where the Examiner fails to set forth a prima facie case of obviousness, the burden to rebut the Examiner's findings and conclusion never shifts to Appellant. *See In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

Here, the Examiner does not make out a prima facie case of obviousness. The Examiner's Final Action and Answer contain no findings of fact or technical analysis concerning the modifications that would have been necessary to transform Bao's disc nucleus prosthesis into a total disc prosthesis. Not only does the Examiner fail to describe such modifications, the Examiner also fails to explain why such modifications would have been obvious to a person of ordinary skill in the art at the time the invention was made. Thus, whether or not Bao could have been modified by the fiber of Stubstad is beside the point. The Examiner's proposed combination, at best, would have merely been a disc nucleus prosthesis that features a fiber element. However, such is not the total disc prosthesis invention that Appellant has disclosed and claimed.

Inasmuch as the Examiner failed to make out a prima facie case of unpatentability, we need not address Appellants' arguments and evidence. We do not sustain the rejection of claims 1, 11, and 16.

Claims 2–6 and 17–19

Claims 2–6 depend from claim 1. Claims App. Claim 17 is an independent claim that is substantially similar to claim 1. *Id.* Claims 18 and 19 depend from claim 17. The Examiner's unpatentability rejection of claims 2–6 and 17–19 suffers from the same infirmity that we have identified above with respect to claim 1. For the same reasons, we do not sustain the rejection of claims 2–6 and 17–19.

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*Unpatentability of Claims 8–16 and 20–28
over combinations based on Bao and Stubstad*

These claims are rejected over Bao and Stubstad in combination with various other references. Final Action 5–8. The Examiner does not rely on these additional references to cure the deficiencies we have noted above with respect to the rejection of claims 1 and 17. For the same reasons, we do not sustain the rejection of claims 8–16 and 20–28.

DECISION

The decision of the Examiner to reject claims 1–6 and 8–28 is reversed.

REVERSED